

Substitute for form 1449A&amp;B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1655
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	ADAMS, M., Declaration of Dr. Michael Adams, including <i>Curriculum Vitae</i> , 22 pages, March 13, 2006.	<input type="checkbox"/>
	2.	AZARNOFF, D.L., Declaration of Daniel L. Azarnoff, M.D., including <i>Curriculum Vitae</i> , 27 pages, October 3, 2003.	<input type="checkbox"/>
	3.	BENET, L.Z. et al., "Section I: General Principles, Chapter 1: Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination" in <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 8th Ed., Pergamon Press, pp.1-32 (1980)	<input type="checkbox"/>
	4.	BOUGHTON-SMITH, N.K., "Nitric Oxide Synthase Activity in Ulcerative Colitis and Crohn's Disease," <i>The Lancet</i> , 342:338-340 (1999)	<input type="checkbox"/>
	5.	CELLEGY PHARMACEUTICALS INC., "Corporate Alliances," 2 pages, undated.	<input type="checkbox"/>
	6.	CHAUDHURI, G. et al., "NO is More Important than PGI <sub>2</sub> in Maintaining Low Vascular Tone in Feto-placental Vessels," <i>Am. J. Physiol.</i> 265 (Heart Circ. Physiol. 34):H2036-43 (1993)	<input type="checkbox"/>
	7.	CONANT, C.C., "Plasma Nitroglycerin Levels, Blood Pressure and Apical Heart Rate Variations to Site of Application of Nitroglycerin Ointment," <i>Nurse Practitioner</i> 13(10):56-64 (1988)	<input type="checkbox"/>
	8.	DOLLERY, C.T., Declaration of Colin T. Dollery, MB, Ch.B. FRCP., including <i>Curriculum Vitae</i> , 63 pages, May 24, 2004.	<input type="checkbox"/>
	9.	ERBA, M. et al., "Nitropaste for Prevention and Relief of Vascular Spasm," <i>AJNR</i> , 10:155-56 (1989)	<input type="checkbox"/>
	10.	FLYNN, G.L., Declaration of Gordon L. Flynn, Ph.D., including <i>Curriculum Vitae</i> , 29 pages, May 21, 2004.	<input type="checkbox"/>
	11.	FLYNN, G.L., "Topical Drug Absorption and Topical Pharmaceutical Systems," <i>Modern Pharmaceuticals</i> , 2d Ed., pp. 263-64, 89 (1990)	<input type="checkbox"/>
	12.	GIBBONS, R.D., Declaration of Robert D. Gibbons, including <i>Curriculum Vitae</i> , 19 pages, May 13, 2002.	<input type="checkbox"/>

Examiner  
Signature

C. R. Tate



Date  
Considered

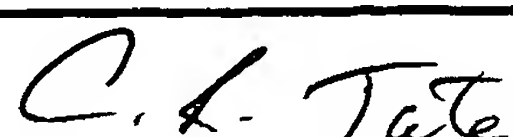
8/7/06

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	2	of	4	Attorney Docket Number	010692-004532US



NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	13.	HADGRAFT, J., "Recent Developments in Topical and Transdermal Delivery," Eur. J. Drug Metab. Pharmacokinetics 21(2):165-73 (1996)	<input type="checkbox"/>	
	14.	KING, D., Declaration of Denis King, 1 page, December 23, 2000	<input type="checkbox"/>	
	15.	KING, D.W., "GTN in the Management of Anal Fissure," presentation slides and cover letter, 9 pages, March 7, 2001	<input type="checkbox"/>	
	16.	L'HOPITAL, F. et al., "Constipation et Hypertonie du Sphincter Interne de L'Anus: Response Sphincterienne A L'Administration Sub-Linguale de 0,40 Mg de Natispray," Gastroenterol Clin Biol 14:268 (1990) with English Translation	<input checked="" type="checkbox"/>	
	17.	LIPTON, S.A. et al., "A Redox-based Mechanism for the Neuroprotective and Neurodestructive Effects of Nitric Oxide and Related Nitroso-compounds," Nature 364:626-32 (1993)	<input type="checkbox"/>	
	18.	LOPEZ-BELMONTE, J. et al., "The Actions of Nitric Oxide Donors in the Prevention or Induction of Injury to the Rat Gastric Mucosa," Br. J. Pharmacol. 108:73-78 (1993)	<input type="checkbox"/>	
	19.	LUND, J.N., Declaration of Mr. Jonathan Lund, including Curriculum Vitae, 29 pages, March 6, 2003.	<input type="checkbox"/>	
	20.	MAHAJAN, R.P. et al., "Topical Nitroglycerin Prevents the Pressor Response to Tracheal Intubation and Sternotomy in Patients Undergoing Coronary Artery Bypass Graft Surgery," Anaesthesia 48:297-300 (1993)	<input type="checkbox"/>	
	21.	MATHEIS, G. et al., "Role of L-arginine-nitric Oxide Pathway in Myocardial Reoxygenation Injury," Am. J. Physiol. 262:H616-20 (1992)	<input type="checkbox"/>	
	22.	MEDICAL ECONOMICS, PHYSICIANS, <u>Physicians' Desk Reference</u> , 46 Edition, pp.1004-1006; 1164-1166 (1992).	<input type="checkbox"/>	
		23.	MERCK & CO., INC., "The Merck Manual of Diagnosis and Therapy, Section 3: Gastrointestinal Disorders, Chapter 35: Anorectal Disorders, General" retrieved online at < <a href="http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp">http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp</a> > on February 14, 2005.	<input type="checkbox"/>

Examiner Signature		Date Considered	8/7/04
-----------------------	---	--------------------	--------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.


Substitute for form 1449A&B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	3	of	4	Attorney Docket Number	010692-004532US


NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	24.	PARTEQ INNOVATIONS, "Cellegy Pharmaceuticals Acquires PARTEQ Spinoff Vaxis," 2 pages, Nov. 28, 2001	<input type="checkbox"/>	
	25.	PAVLICK, K.P. et al., "Role of Reactive Metabolites of Oxygen and Nitrogen in Inflammatory Bowel Disease," Free Radical Biology & Medicine 33(3):311-322 (2002)	<input type="checkbox"/>	
	26.	PIAZZA, C.T., Declaration of Christin T. Piazza, 2 pages, May 15, 2002	<input type="checkbox"/>	
	27.	RANADE, V.V., "Drug Delivery Systems. 6. Transdermal Drug Delivery," J. Clin. Pharmacol. 31:401-418 (1991)	<input type="checkbox"/>	
	28.	ROMANELLI, M. et al., "The Effect of Topical Nitroglycerin on Transcutaneous Oxygen," British Journal of Dermatology 124:354-357 (1991)	<input type="checkbox"/>	
	29.	SANDRINI, A. et al., "Effect of Montelukast on Exhaled Nitric Oxide and Nonvolatile Markers of Inflammation in Mild Asthma," CHEST 124:1334-1340 (2003)	<input type="checkbox"/>	
	30.	SCHOLEFIELD, J.H. et al., "A Dose Finding Study with 0.1%, 0.2%, and 0.4% Glyceryl Trinitrate Ointment in Patients with Chronic Anal Fissures," Gut 52:264-69 (2003)	<input type="checkbox"/>	
	31.	SCHOLEFIELD, J.H., Declaration of John Howard Scholefield, including Curriculum Vitae, 47 pages, Feb. 28, 2005.	<input type="checkbox"/>	
	32.	SCHOUTEN, W.R., "Pathophysiological Aspects and Clinical Outcome of Intra-Anal Application of Isosorbide Dinitrate in Patients with Chronic Anal Fissure," Gut 39(6):465-469 (1996)	<input type="checkbox"/>	
	33.	SHERMAN, M.P., "Nitric Oxide-Mediated Neuronal Injury in Multiple Sclerosis," Medical Hypotheses 39:143-146 (1992)	<input type="checkbox"/>	
34.	SHIVELY, M., "Effect of Nitroglycerin Ointment Placement on Headache and Flushing in Healthy Subjects," Int. J. Nurs. Stud., 28(2):153-161 (1991)	<input type="checkbox"/>		
	35.	VAN REEMPTS, P. et al., "Topical Use of Nitroglycerin Ointment in Neonates," Editorial Correspondence, J. Pediatr, 116(1):155 (1990)	<input type="checkbox"/>	
Examiner Signature	C. R. Tate		Date Considered	8/7/06

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Application Number</b>	10/669,099
				<b>Filing Date</b>	September 22, 2003
				<b>First Named Inventor</b>	Gorfine, Stephen R.
				<b>Art Unit</b>	1655
				<b>Examiner Name</b>	Tate, Christopher Robin
<b>Sheet</b>	4	of	4	<b>Attorney Docket Number</b>	010692-004532US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	36.	WEINHARDT, J.A., "Making the Most of Topical Nitroglycerin," RN 48(12):38-40 (1985)	<input type="checkbox"/>

<b>Examiner Signature</b>		<b>Date Considered</b>	8/7/06
-------------------------------	---	----------------------------	--------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/APTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

4


**Complete if Known**

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1655
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	1.	ZA	9500511	A	03-11-1996	Koren Lab Pty Ltd		<input type="checkbox"/>
								<input type="checkbox"/>

Examiner  
Signature

C. R. Tate




Date  
Considered

8/7/06

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.




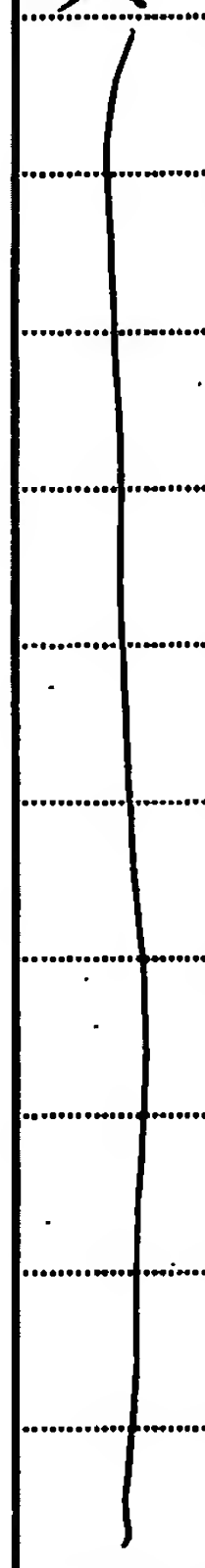

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	2	of	4	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
  	2.	ANONYMOUS, "ASCRS Registrants: 92nd Annual Convention - May 2-7, 1993, Hyatt Regency Chicago, Chicago, IL," List of Registrants, 34 pages [Exhibit PBL-9 to the Loder Declaration]	<input type="checkbox"/>	
	3.	ANONYMOUS, "Royal Australian College of Surgeons and Australian and New Zealand College of Anaesthetists Annual Scientific Congress- Adelaide 1993: Statistics at 14/5/93" and "A.S.C. Adelaide 1993 Scientific Programme: 10-14 May, 1993" Proceedings excerpts, 5 pages [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	4.	BROOKES, S., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>	
	5.	CRISTOFANI, K., "Anal fissures treated: Topical glyceryl trinitrate may play an important role in the management of anal fissures, US surgeons say," Australian Doctor, October 4, 1996.	<input type="checkbox"/>	
	6.	HOWES, L.G., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000, with Curriculum Vitae of Lawrence Guy Howes as Exhibit LGH-1 (26 pages).	<input type="checkbox"/>	
	7.	JONES, I.T., "The solitary rectal ulcer," presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	8.	KAMM, M.A. et al., "The Sir Alan Parks Physiology Unit," St. Mark's Hospital Year Book, St. Mark's Hospital, London, U.K., 2 pages [Exhibit PBL-14 to the Loder Declaration]	<input type="checkbox"/>	
	9.	KENNEDY, M.L., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000	<input type="checkbox"/>	
	10.	LODER, P.B., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Koren Laboratories Pty Limited -and- In the Matter of Opposition thereto by Peter Loder," October 11, 2000, 37 pages; with Exhibits PBL-2, 5, 8, 9, 11, 12, 14, 19, and 22-25.	<input type="checkbox"/>	
	11.	LODER, P.B., "Curriculum Vitae of Peter Bruce Loder" October 11, 2000, 14 pages [Exhibit PBL-2 to the Loder Declaration]	<input type="checkbox"/>	
	12.	LODER, P.B., "Application for Ethical Approval of Pilot Study" October 11, 2000, 15 pages [Exhibit PBL-8 to the Loder Declaration]	<input type="checkbox"/>	
	13.	LODER, P.B. et al., "Reversible chemical sphincterotomy by topical application of glyceryl trinitrate (GTN)," St. Mark's Hospital, London, U.K., presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	Examiner Signature	C. R. Tate		Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	3	of	4	Attorney Docket Number	010692-004532US

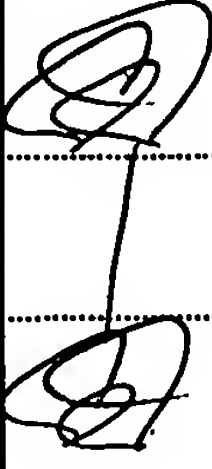
NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
 	14.	LODER, P.B. et al., "A new den for the winged lion: St. Mark's at Northwick Park," St. Mark's Hospital, London, U.K., presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	15.	LODER, P.B., Presentation Slides, May 13-14, 1993, 14 pages [Exhibit PBL-12 to the Loder Declaration]	<input type="checkbox"/>	
	16.	LODER, P.B., Letter to Dr. D.Z. Lubowski re discussion of GTN, 2 pages, July 18, 2000 [Exhibit PBL-22 to the Loder Declaration and Exhibit DZL-14 to the Lubowski Declaration]	<input type="checkbox"/>	
	17.	LODER, P.D., Email message to John Scholefield re GTN + Warts, 2 pages, August 1, 1998 [Exhibit PBL-23 to the Loder Declaration]	<input type="checkbox"/>	
	18.	LODER, P.D., Type-written notes re telephone conversations with D. Z. Lubowski, November 11, 1999 and November 28, 1999, 2 pages [Exhibit PBL-25 to the Loder Declaration]	<input type="checkbox"/>	
	19.	LUBOWSKI, D.Z., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Limited -and- In the Matter of Opposition thereto by Peter Bruce Loder," October 16, 2000, 14 pages; with Exhibits DZL-1, 9, and 14]	<input type="checkbox"/>	
	20.	LUBOWSKI, D.Z., "Curriculum Vitae of David Z. Lubowski," 38 pages, October 16, 2000 [Exhibit DZL-1 to the Lubowski Declaration]	<input type="checkbox"/>	
	21.	LUBOWSKI, D.Z. et al., "A radio-isotope study of colonic function during defaecation," St. George Hospital, Sydney, presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	22.	LUBOWSKI, D.Z., "Anorectal physiology - Is it useful in rectal prolapse?," St. George Hospital, Sydney, presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	23.	LUBOWSKI, D.Z., Letter to Dr. P. B. Loder re discussion of GTN with reply by Peter B. Loder, 3 pages, July 25, 1998 [Exhibit DZL-14 to the Lubowski Declaration and Exhibit PBL-22 to the Loder Declaration]	<input type="checkbox"/>	
24.	MARCHEI, C., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>		
	25.	PHILLIPS, R.K.S., Letters dated October 29, 1998 and May 12, 1998 regarding invitation to lecture at St. Mark's Hospital, 7 pages [Exhibit DZL-9 to the Lubowski Declaration]	<input type="checkbox"/>	

Examiner Signature	C. R. Tate	Date Considered	8/7/04
-----------------------	------------	--------------------	--------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	4	of	4	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	26.	SCHOLEFIELD, J., Email messages to Peter Loder, including 1 from Peter Stein, regarding Gorfine patent application, 4 pages, April 1, 1997 [Exhibit PBL-19 to the Loder Declaration]	<input type="checkbox"/>	
	27.	SCHOUTEN, W.R., "Lateral internal sphincterotomy in the treatment of Hemorrhoids: A clinical and manometric study" Dis Colon Rectum 29:869-72 (1986) [Exhibit PBL-5 to the Loder Declaration]	<input type="checkbox"/>	
	28.	STEIN, P.M., Letter to Dr. Peter B. Loder regarding circumstances surrounding meeting, 3 pages, September 18, 2000 [Exhibit PBL-24 to the Loder Declaration]	<input type="checkbox"/>	
				<input type="checkbox"/>

Examiner Signature	C. R. Tate	Date Considered	8/7/04
-----------------------	------------	--------------------	--------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.